Innodent User manual

Sterile Dental Hand Instrument Instructions for Use (IFU)

Indications

Diseases and condition that lead to the necessity of extracting retained dental root fragments such as tooth breakage whether due to accidents or diseases and conditions (these are the type of conditions that are usually addressed via invasive surgical methods).

Intended use

A hole must be drilled inside the retained root fragment using the already available standard dental drills in the dental clinic. EMB Pro's dental bur is placed inside the drilled hole. Using the provided screw that can be locked on top of the bur's head, EMB Pro would expand to fit perfectly inside the hole, forming an anchor. The screw is then detached from the bur. Before attaching the extraction device's main body to the rails, the appropriate placement support bar based on the size of the tooth being treated must be placed on the rails. The rails have an indentation that the support bars can be fit into. An extraction device is placed on top of the retained root fragment and the other two adjacent teeth. The device is locked onto the bur's head. It must then be adjusted in accordance with the diameter of the teeth it has been placed on using the provided screw that is placed on the side of the device. Furthermore, the plate on top of the extraction device must also be adjusted to form a 90-degree angle using the 4mm screws on the back of the main device. The rope placed where the handle is attached to the main part of the device has a spherical structure that allows it to become latched in either one of the bridges on the handle, depending on the required height in relation to the EMB Pro. The large screw placed at the back of the handle must be twisted to extract the root fragment.

The sterilization process for EMB Pro is in accordance with IPAC guidelines for dental hand instruments.

Cautions and Precautions

InnoDent Dental Technologies Ltd. dental burs and extraction device should only be used by dentists adequately qualified and trained in dental treatment procedures; dental laboratory use should be limited to adequately qualified and trained technicians.

Precautions:

Dentists must consider all comorbidities, past and present, medications, previous treatments, and existing condition in using the EMB Pro (as an example root extraction is generally not advisable for patients with hemophilia).

- The bur piece must be sterilized after each use
- Burs must be disposed/discarded according to local authority regulations and environmental requirements or returned to the manufacturer, if so instructed.

- In case a defect is observed in the extraction device the manufacturer must be contacted for recommendations on safe return of devices.
- Gloves must be worn at all times when handling contaminated burs.
- Surgical mask must be worn due to existence of open wound in the mouth of the patient.

Warnings

- Prior to using the bur, sterilization of the bur and the extraction device is necessary in order to eliminate any chances of the occurrence of infections.
- Use only Steam Sterilization method that is in accordance with IPAC guidelines and keep the device in appropriate sterilization pouches until next use.

Contraindications

Use of the dental hand instruments for the purpose of root extraction is associated with a general dental restorative procedure, which may include, according to local practice, administration of anesthetic agents, preceding the procedure, and antibiotic prophylaxis, administered prior to or after the procedure. Consequently, the following contraindications apply to the procedure:

- Renal failure
- Steroid use
- Systolic pressure above 170 and/or diastolic pressure above 110 mmHg
- Patients receiving corticosteroid, anticonvulsive, or immunosuppressive therapy
- Organ transplantation
- Abnormal values for blood urea nitrogen or creatinine
- Anticoagulation therapy
- Granulocytopenia
- Hemophilia

Aside of hypersensitivity to the dental burs' components, i.e., stainless steel there are no contraindications that apply to use of the dental burs and the extraction device.

Patient populations

Children, adolescents, and adults.

NOTE ON THE DEFINITION OF "CHILDREN" FOR THE PURPOSES OF THIS EVALUATION: Considering the apparent dissonance in terminology, with "children" and "pediatric patients" oftentimes used interchangeably, and the fact that definitions of these populations vary in different jurisdictions, it is important to note the differences for regulatory purposes. In the European Union, MDD and MDR lack definitions on pediatric patients. MDR also does not discern between a "minor" and a "child" in Article 65 and does not contain definitions for either. Title 1 Chapter 1 Article 2.1) of Regulation (EC) No 1901/2006

on medicinal products for pediatric use defines 'pediatric population' as part of the population aged between birth and 18 years, while Regulation 536/2014 (Article 2(2.18)) defines a "minor" (and unlike the

ICH E11 guideline, does not discern between a "minor" and a "child"1) as: "a subject who is, according to the law of the Member State concerned, under the age of legal competence to give informed consent." The age of legal competence differs across national laws, for example adolescents from 16 years of age may not be regarded as minors in some Member States. In the United States, 21 CFR 56.111 refers to children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons as vulnerable populations. Children are defined in 21 CFR 50.3(o) as persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. This definition differs from the definition of children provided in the ICH E11 Note for Guidance on Clinical Investigation of Medicinal Products in The Paediatric Population (CPMP/ICH/2711/99), in which "children" is a term defining a subgroup of pediatric patients aged 2-11 years. In the drug regulations, namely in 21 CFR 201.57(c)(9)(iv)(A) and 201.80(f)(9)(i), the terms pediatric population(s) and pediatric patient(s) are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents. However, 21 U.S.C. § 360j(m)(6)(E)(i) and (ii) (incorporating Section 520m(6)E(i) and (ii) of the Food, Drug, and Cosmetic Act) define pediatric patients as age 21 years or younger at the time of diagnosis or treatment and specify categories of pediatric subpopulations:

- (I) Neonates.
- (II) Infants.
- (III) Children.
- (IV) Adolescents.

Further, 21 U.S.C. § 360e-1(a) (Section 515A of the FD&C Act) uses the same definition of "pediatric subpopulations." Accordingly, for medical device, the US FDA interprets the statutory definition of pediatrics as individuals who are 21 years of age or younger, that is, from birth through the 21st year of life, up to but not including the 22nd birthday (21 CFR 814.3(s)). Consequently, EMB Pro is not intended to be used in "newborns" (or neonates), i.e., pediatric patients from birth to 16 years of age.

Intended users

Dentists adequately qualified and trained in dental restorative procedures.

General burs' operation instructions

- Remove sterile device from packaging. Use aseptic technique.

- Do not force the bur to lock into either the extraction mechanism or expanding screw. In case of difficult access, check both ends of the device. In case there is a defect in the device they shall be replaced if found incompatible in accordance with our user guarantee. However, special attention should be paid to instructions of use and maintenance of the device.

EMB Pro operation instruction

- Insert EMB Pro inside a suitably drilled hole in a retained dental root fragment.

- Using the screw mechanism that self-locks into the bur, the bur's head must be expanded to form a firm grip on the dental root.
- The screw must then be unattached from the bur head.
- The extraction device must be place on top of the bur and the two adjacent teeth. It must then be fixed on its location in accordance with the width of the teeth is has been placed on using the screws at the sides of the device.
- Please note that for front teeth prior to fixing the device on the teeth two silicon bars that have been provided in the package must be placed on the part of extraction device that is going to be in contact with the teeth in order to form a firmer grip.
- The bur must then be locked into the extraction device. The plate on top of where the bur is locked into the device enables the dentist to adjust the angle of the hole device to form a 90-degree angle with the root being extracted using a 4 mm screw provided at the back of the main part of the device.
- The rope placed where the handle is attached to the main part of the device has a spherical structure that allows it to become latched in either one of the bridges on the handle depending on the required height in relation to the EMB Pro.
- The large screw at the back of the handle can be used to complete the extraction process.

Storage

- Keep the devices in their sterile original packaging in a dry and clean environment, at room temperature prior to first usage. After the first use, the sterilization process mentioned above must be completed and the devices must be placed inside sterilization pouches and kept at room temperature.

INSPECTION

Assemble the device(s) (e.g. extraction device(s), when applicable) and carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process. Discard bur(s) which show deformations (bent, twisted), damages (broken, corroded) or another visible defect.

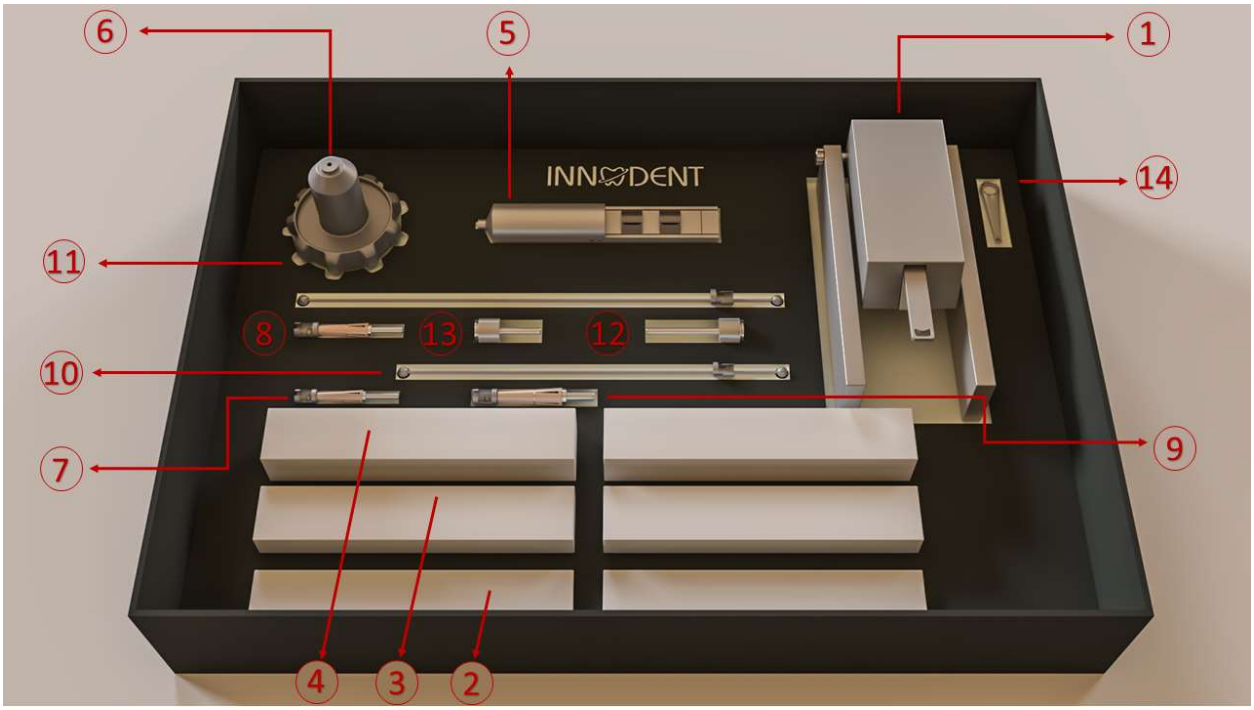
PACKAGING

Device(s) should be packed in a medical grade sterilization pouch (compliant to EN ISO 11607-1) or wrapped suitably for the recommended specifications for steam sterilization provided in the section below.

Package Components:

- Extraction Device Holder
- Placement Support Bars 2 mm
- Placement Support Bars 5 mm
- Placement Support Bars 8 mm
- Device's Handle
- Large Sized Extraction Screw

- Bur Ø 1.6 mm, Short 10 mm
- Bur Ø 1.6 mm, Long 18 mm
- Bur Ø 1.8 mm, Short 10 mm
- Pullrope 70 mm
- Pullrope 85 mm
- Long Expansion Screw
- Short Expansion Screw
- Double-Sided Ring Wrench



STORAGE

Sterile packaged device(s) should be stored in a well-ventilated area and protected from dust, moisture, insects and temperature/humidity extremes. Sterile device(s) packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

Symbols Interpretation

- Symbols on the product package should be interpreted as follows:

	Use-by date (expiration date)		Batch code number	
	Consult operating instructions		Catalogue number	
	Do not use if package is opened or damaged and/or if sterile barrier is compromised		Manufacturer	
	Sterilized using Steam and Dry Heat		Date of manufacture	
	Non-Sterile (to distinguish between similar devices that are provided as non-sterile from sterile labeled devices)		CE-Mark Symbol	
	Authorized Representative in the European Community			
	Medical device symbol			